GHSC-PSM Global Standards & Traceability Regulation Tracker

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Introduction

This document is intended to share a general summary of requirements for standardized **identification**, **data capture**, and **data sharing** from low- and middle-income countries (LMICs) and international procurement agents.

For more information on individual requirements, please follow links to the full regulations or guidelines. This document is intended only as a preliminary summary and not an exhaustive overview of guidelines.

Key Considerations

Timelines

When will entities be expected to comply with requirements?

Packaging Levels

What packaging levels will be subject to the requirements and how will compliance deadlines differ between these?

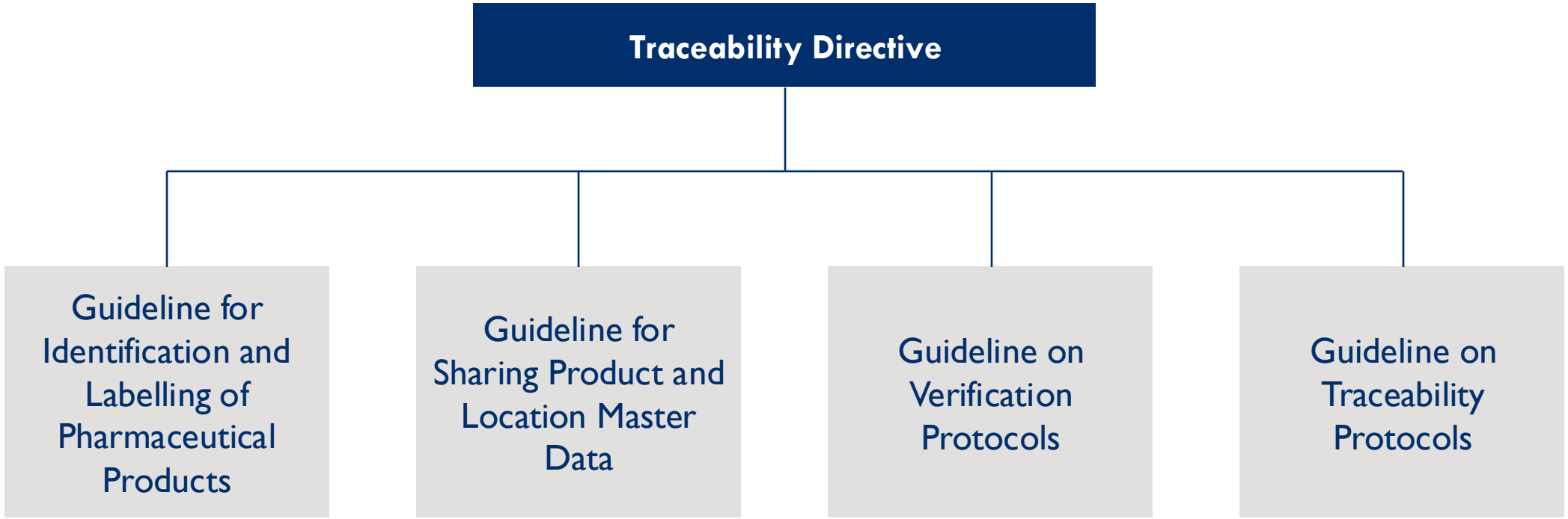
Product Scope

Which products will initially be subject to the requirements?

Identification and Data Carrier Requirements

What data carriers and application identifiers will be required at each packaging level?
Will serialization be in-scope?
How will these align with global standards?

Illustrative Regulatory Components



- The "WHAT" — the *Traceability Directive* is the overall legal framework that mandates and enforces pharmaceutical traceability.
- The "HOW" — a series of guidelines that support supply chain actors with additional details on how to implement the mandate in accordance with standards. The guidelines may be adjusted over time as additional capabilities are deployed and lessons learned captured through implementation.

Key Definitions: Packaging Levels

Tertiary Packaging

Tertiary packaging refers to the outermost layer of packaging used for logistics and/or trade, typically involving pallets or cases, and may contain homogenous, partial, or mixed items.

Secondary Packaging

Secondary packaging holds one or more primary packages, is always considered a trade item, and is typically marked with a GS1 DataMatrix on the packaging or its label.

Primary Packaging

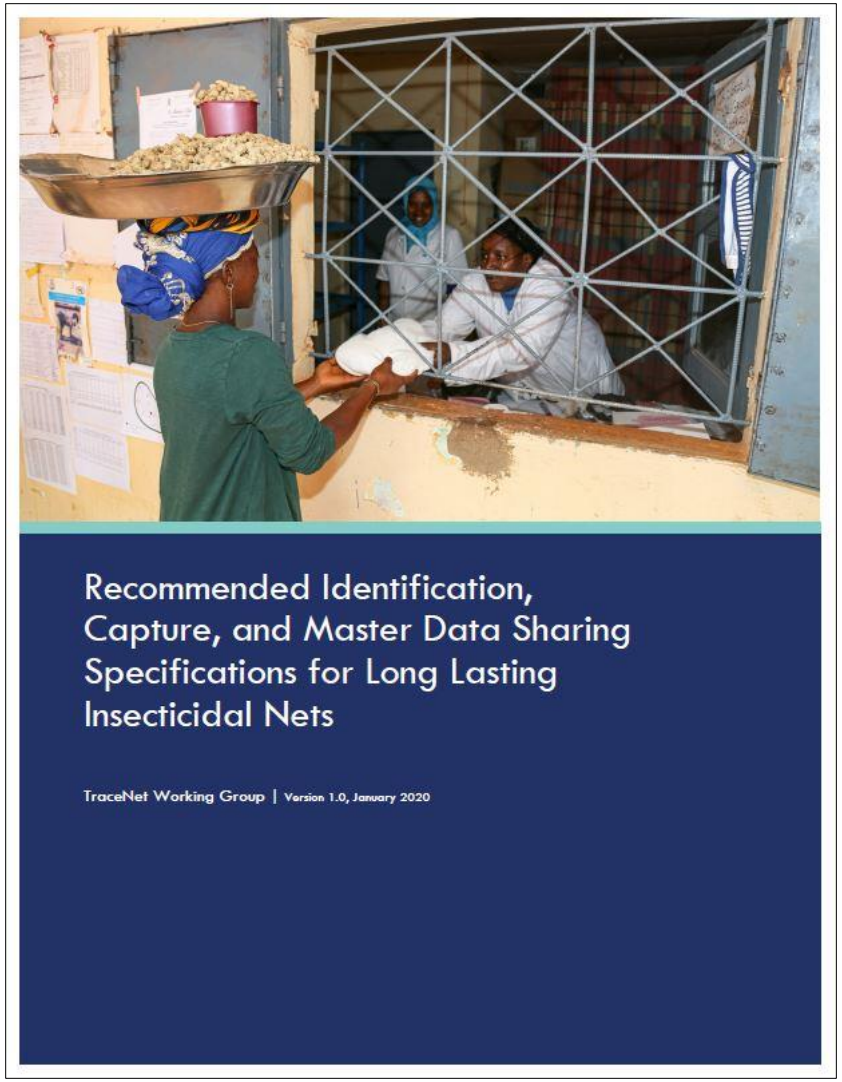
Primary packaging is the first packaging layer in direct contact with the item, optionally marked with a GS1 DataMatrix (typically required in cartonless packaging and recommended when secondary packaging is likely to be opened or removed before dispensing).

International Procurement Agent (IPA) Global Standards Technical Implementation Guidelines

Summary of Documents

These multi-agency documents establish harmonized standards and phasing for global standards implementation but leave specific timelines and requirements up to each endorsing agency

See also: UNICEF specifications on packaging palletization and labelling



Overview of Requirements: Pharmaceuticals, Medical Devices, and Vaccines

IDENTIFY		
Entity	**Requirement**	**Phase**
Trade items	Assign and provide Global Trade Item Numbers (GTINs) for all levels of the packaging hierarchy including each, inner pack, intermediate pack, case, and pallet (if trade item).	Phase 1
Locations and/or legal entities	Assign and provide Global Location Numbers (GLNs) for legal entities or organizational functions (sold-from, data synchronization) and physical locations (manufacture-from, ship-from) pertinent to the trade item.	Phase 1

SHARE			
Data type	**Scope**	**Requirement**	**Phase**
Master data	Trade items	Provide mandatory and required attribute data via the GDSN	Phase 2
Event data	Trade items; logistic units	Provide IPA with serialization data within 30 days upon request	Phase 4

CAPTURE				
Packaging level	**Packaging type**	**Data Carrier**	**Encoded data and human readable interpretation (HRI)***	**Phase**
Tertiary: logistic unit	Logistic unit is also a trade item	GS1-128 linear barcode	• (00) Serial Shipping Container Code (SSCC) • (01) GTIN • (10) Batch/lot • (17) Expiration date	Phase 1 for GTIN, batch/lot and expiration date Phase 3 for SSCC
	Logistic unit containing homogenous trade items	GS1-128 linear barcode	• (00) SSCC • (02) GTIN of contained trade items • (37) Count of contained trade items • (10) Batch/lot • (17) Expiration date	Phase 3 for SSCC Phase 5 for GTIN, batch/lot, count and expiration date
	Logistic unit containing heterogeneous trade items	GS1-128 linear barcode	• (00) SSCC	Phase 3
Tertiary: trade item	Homogenous	GS1 DataMatrix or GS1-128 linear barcode	• (01) GTIN • (10) Batch/lot • (17) Expiration date • (21) Serial number***	Phase 1 for GTIN, batch/lot, and expiration date Phase 4 for serial number
Secondary: trade item		GS1 DataMatrix	• (01) GTIN • (10) Batch/lot • (17) Expiration date • (21) Serial number***	Phase 3 for GTIN, batch/lot, and expiration date Phase 4 for serial number
Primary: trade item This characteristic is strongly preferred but required only when no secondary pack labelling exists, such as in the case of cartonless/bulk packaging		GS1 DataMatrix	• (01) GTIN • (10) Batch/lot • (17) Expiration date • (21) Serial number	If required: Phase 3 for GTIN, batch/lot, and expiration date Phase 4 for serial number

***Only required for Pharmaceutical products
*See barcode requirements for more information

Overview of Requirements: Long-Lasting Insecticidal Nets (LLIN)

IDENTIFY		
Entity	**Requirement**	**Phase**
Trade items	Assign and provide Global Trade Item Numbers (GTINs) for LLIN	Phase 1
Locations and/or legal entities	Assign and provide Global Location Numbers (GLNs) for legal entities or organizational functions (sold-from, data synchronization) and physical locations (manufacture-from, ship-from) pertinent to the trade item.	Phase 1

SHARE			
Data type	**Scope**	**Requirement**	**Phase**
Master data	Trade items	Provide mandatory and required attribute data via the GDSN	Phase 2
Event data	Trade items; logistic units	Retain event data for a minimum of six (6) years after product leaves supplier custody and to provide this data within 30 days of a request in a mutually agreeable format	Phase 3

Overview of Requirements: LLINs

CAPTURE			
Packaging level	**Data Carrier**	**Encoded data and human readable interpretation (HRI)***	**Phase**
Bale	GS1-128 linear barcode	• (00) SSCC • (02) GTIN of contained items • (37) Count of contained Items • (11) Production Date • (10) Batch/Lot Number	Phase 3
Bag with LLIN	GS1 DataMatrix	• (01) GTIN • (10) Batch/lot • (11) Production Date • (21) Serial number	Phase 2
Individual LLIN	GS1 DataMatrix	• (01) GTIN • (10) Batch/lot • (11) Production Date • (21) Serial number	Phase 2 for GTIN, Batch/Lot, and Production Date; Phase 3 for Serial Number

Important Notes for Implementation Timelines

- Development of GS1 phase requirements has grown over the years in accordance with the trends found within the supply chain.
- Each Agency has its own unique history of adoption, but they remain cohesive and aligned with the greater global health community.
- "Voluntary but Preferred" recommends a suggestion that is not required, but is aligned with active community requirements

Implementation Timelines

While requirements are aligned, implementation timelines vary by donor. Current implementation timelines are as follows:

	Agency	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Pharmaceuticals	GDF/Stop TB	30 Dec 2019	30 Dec 2019	30 June 2022	30 June 2022	Voluntary but Preferred
	UNDP	Voluntary but preferred	Voluntary but preferred	Voluntary but preferred	Voluntary but preferred	Voluntary but preferred
	UNFPA	Voluntary but preferred	Voluntary but preferred	Voluntary but preferred	Voluntary but preferred	Voluntary but preferred
	USAID	30 Dec 2018	30 Dec 2019	30 Jun 2020	30 Jun 2022	30 Dec 2024
Vaccines	UNICEF	Voluntary but preferred	Voluntary but preferred	31 Dec 2021	Voluntary but preferred	Voluntary but preferred
	USAID	30 Dec 2018	30 Dec 2019	30 Jun 2020	30 Jun 2022	30 Dec 2024
Lab/Medical	GDF/Stop TB	Voluntary but preferred	Voluntary but preferred	Voluntary but preferred	Voluntary but preferred	Voluntary but preferred
	UNDP	Voluntary but preferred	Voluntary but preferred	Voluntary but preferred	Voluntary but preferred	Voluntary but preferred
	UNFPA	Voluntary but preferred	Voluntary but preferred	Voluntary but preferred	Voluntary but preferred	Voluntary but preferred
	USAID	30 Dec 2018	30 Dec 2019	30 Jun 2020	30 Jun 2022	30 Dec 2024
LLINs	The Global Fund	30 Jun 2020	30 Dec 2020	30 Jun 2022	N/A	N/A
	USAID/PMI	30 Jun 2020	30 Dec 2020	30 Jun 2022	N/A	N/A

Rwanda Regulation Summary

Summary of Regulatory Documents: Rwanda

Regulations Governing the Implementation of Identification, Data Capture and Data Sharing for Traceability of Pharmaceutical Products
Published in August 2022

Guidelines for Identification and Labelling of Pharmaceutical Products
Published in August 2022

Guidelines for Product and Location Master Data Sharing
Published in August 2022

Summary of Regulatory Documents: Rwanda

Regulations Governing the Implementation of Identification, Data Capture and Data Sharing for Traceability of Pharmaceutical Products
Published in August 2022

Guidelines for Identification and Labelling of Pharmaceutical Products
Published in August 2022

Guidelines for Product and Location Master Data Sharing
Published in August 2022

Key Sections:

- Regulation Development History
- Adoption & Approval of the Regulations
- General Provision: Purpose, Application, and Definition of the Regulations
- Technical Specifications of the Unique Identifier
- Master Data Sharing and Traceability System

Summary of Regulatory Documents: Rwanda

Regulations Governing the Implementation of Identification, Data Capture and Data Sharing for Traceability of Pharmaceutical Products
Published in August 2022

Guidelines for Identification and Labelling of Pharmaceutical Products
Published in August 2022

Guidelines for Product and Location Master
Published in Aug

Key Sections:

- Product Identification and Labelling Requirements for Pharmaceuticals
- Description of Packaging Levels
- Overview of Relevant Global Standards: Identify, Capture

Summary of Regulatory Documents: Rwanda

Regulations Governing the Implementation of Identification, Data Capture and Data Sharing for Traceability of Pharmaceutical Products
Published in August 2022

Guidelines for Identification and Labelling of Pharmaceutical Products
Published in August 2022

Guidelines for Product and Location Master Data Sharing
Published in August 2022

Key Sections:
- Master Data Attribute Requirements
- Steps for Synchronizing Master Data
- Data Synchronization Resources

Regulatory Summary: Identification & Labeling

Packaging Type	Requirement	Deadline
Secondary package of authorized pharmaceutical products	GS1 DataMatrix encoded with GTIN, Expiration Date, Batch/Lot, and Serial Number	GTIN, Expiration, Batch/Lot: August 2025 Serial Number: August 2026
Tertiary package of authorized pharmaceutical products	GS1 DataMatrix and/or GS1-128 encoded with GTIN, Expiration Date, Batch/Lot, and Serial Number	GTIN, Expiration, Batch/Lot: August 2025 Serial Number: August 2026
Logistic Unit	SSCC encoded as stated in the GS1 General Specifications Where the logistic unit is an orderable trade item, the logistic unit shall be identified with an SSCC and/or a GTIN	March 2025

Regulatory Summary: Data Sharing

Requirement	Details	Deadline
Master Data: GTIN-based product master data for each level of the trade item packaging hierarchy. GLN for relevant locations and legal entities, including brand owner, manufacturing location, and MAH.	64 attributes, including 13 required attributes and 51 optional attributes, to be shared with Rwanda FDA in Excel format along with marketing authorization application or by email.	Ongoing Market Authorization Holders (MAHs) are expected to share an updated template reflective of changes to master data within 30 days of implementing change.
Event Data	All actors of the pharmaceutical supply chain shall establish a system to electronically record and communicate data including location, date and time and event occurring corresponding to traceability events. All actors of the pharmaceutical supply chain shall record and communicate traceability data to a national traceability system.	TBD The Authority shall issue guidelines for the specification on how to comply with the traceability requirements and how to connect to the national traceability system.

Ethiopia Regulation Summary

Summary of Regulatory Documents: Ethiopia

Pharmaceutical Products Traceability Directive
Passed in August 2019

Pharmaceutical Products Barcoding Guideline
Passed in December 2021

Pharmaceutical Products Traceability Master Data Guideline
Passed in January 2022

Summary of Regulatory Documents: Ethiopia

Pharmaceutical Products Traceability Directive
Passed in August 2019

Pharmaceutical Products Barcoding Guideline
Passed in December 2021

Pharmaceutic Products Traceability Master Data Guideline
Passed in January 20

Key Sections:

- Unique Identification
- Data Carrier
- Human-Readable Interpretation
- Master Data
- Traceability

Summary of Regulatory Documents: Ethiopia

Pharmaceutical Products Traceability Directive
Passed in August 2019

Pharmaceutical Products Barcoding Guideline
Passed in December 2021

Pharmaceutical Products Traceability
Passed

Key Sections:

- Barcoding Requirements: GS1 DataMatrix, Shape and Size, Number of Symbols, Placement, Readability,
- Data Encoding
- Application Identifier
- Printing Instructions & Process
- Aggregation
- Human Readable Interpretation (HRI)
- Verification

Summary of Regulatory Documents: Ethiopia

Pharmaceutical Products Traceability Directive
Passed in August 2019

Pharmaceutical Products Barcoding Guideline
Passed in December 2021

Pharmaceutical Products Traceability Master Data Guideline
Passed in January 2022

Key Sections:

- Master Data Requirements
- Master Data Exchange
- Synchronization with EFDA's Traceability System
- Roles and Responsibilities of Supply Chain Stakeholders

Regulatory Summary: Identification & Labeling

Packaging Type	Requirement	Deadline
Primary Pack Trade Item	*Required only for specified packaging types, including bottles/jars:* GS1 DataMatrix encoded with GTIN, Expiration Date, Batch/Lot, and Serial Number *Note that accompanying HRI is optional on primary pack*	*Authority to publish product lists with associated effective dates, in general:* GTIN: August 2021 Batch/Lot, Expiry: August 2021 for imported products, August 2022 for locally manufactured products Serial Number: March 2025
Secondary pack trade item	GS1 DataMatrix encoded with GTIN, Expiration Date, Batch/Lot, and Serial Number	*Authority to publish product lists with associated effective dates, in general:* GTIN: August 2021 Batch/Lot, Expiry: August 2021 for imported products, August 2022 for locally manufactured products
Tertiary pack trade item	GS1-128 or GS1 DataMatrix encoded with GTIN, Expiration Date, Batch/Lot, and Serial Number	*Authority to publish product lists with associated effective dates, in general:* GTIN: August 2021 Batch/Lot, Expiry: August 2021 for imported products, August 2022 for locally manufactured products
Logistic Unit	GS1-128 encoded with SSCC	March 2025

Regulatory Summary: Data Sharing

Requirement	Details	Deadline
Master data: GTIN-based product master data for trade items and logistic units GLN for legal, functional, manufacturing, receipt, and distribution locations	Products: 30 attributes, including 19 required attributes, to be shared with EFDA system manually or automatically Locations: 11 attributes, including 9 required attributes, to be shared with EFDA system manually or automatically	August 2021
Event and transaction data	Defined events/transactions to be shared with National Traceability System	Batch Traceability (manufacturer, wholesaler, and healthcare provider): August 2023 All supply chain actors: August 2024 Serialized traceability: March 2027

Zambia Regulation Summary

Summary of Regulatory Documents: Zambia

Guideline on Traceability of Medicines

General policy under which ZAMRA is authorized

Guidelines on Identification and Labelling of Medicines and Allied Substances and Master Data Sharing

Published July 2023

Summary of Regulatory Documents: Zambia

Guideline on Traceability of Medicines

Guidelines on Identification and Labelling of Medicines and Allied Substances and Master Data Sharing
Published July 2023

Key Sections:

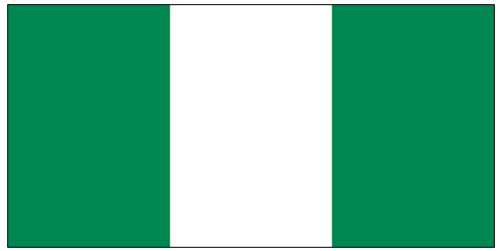
- Description of Packaging Levels
- Requirement for Pharmaceutical Product Identification and Labeling
- Requirements for Medicines and Allied Substances and Location Master Data Sharing
- ZAMRA Product and Location Attribute Guide and Submission Form

Regulatory Summary: Identification & Labeling

Packaging Type	Requirement	Deadline
Primary Pack Trade Item	*Required for cartonless packaging, preferred for other product:* GS1 DataMatrix encoded with GTIN, Expiration Date, Batch/Lot, and Serial Number	GTIN, Expiration Date, and Batch/Lot: July 2025 for imported product, July 2026 for domestically-manufactured product Serial Number: July 2028
Secondary pack trade item	GS1 DataMatrix encoded with GTIN, Expiration Date, Batch/Lot, and Serial Number	GTIN, Expiration Date, and Batch/Lot: July 2025 for imported product, July 2026 for domestically-manufactured product Serial Number: July 2028
Tertiary pack trade item	GS1-128 or GS1 DataMatrix encoded with GTIN, Expiration Date, Batch/Lot, and Serial Number	GTIN, Expiration Date, and Batch/Lot: July 2025 for imported product, July 2026 for domestically-manufactured product Serial Number: July 2028
Logistic Unit	GS1-128 encoded with SSCC	July 2028

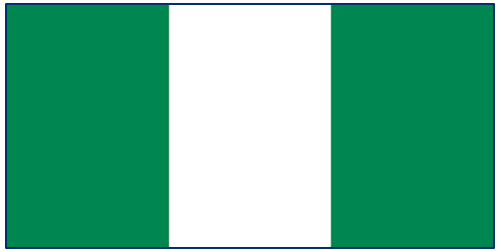
Regulatory Summary: Data Sharing

Requirement	Details	Deadline
Master data linked to GTINs and GLNs	65 attributes, including 13 mandatory attributes, to be shared with ZAMRA via Excel-based form during registration process	*Not published at this time*



Nigeria Regulation Summary

Summary of Regulatory Documents: Nigeria



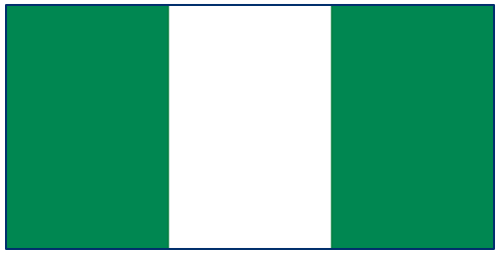
Traceability of Pharmaceutical Products Regulation
Published in October 2024

Registration and Regulatory Affairs Directorate: Label Guidance

Guidelines for Registration of Drug Products Made in Nigeria
Last Reviewed May 2023

Guidelines for Registration of Imported Drug Products in Nigeria
Last Reviewed May 2023

Summary of Regulatory Documents: Nigeria



Traceability of Pharmaceutical Products Regulation
Published in October 2024

Key Sections:
- Unique Identification: Definition and Composition
- Data Carrier Details
- Human Readable Interpretation
- Master Data
- Traceability – Data Capture and Share
- Data Aggregation
- Reporting

Registration and Regulatory Affairs Directorate: Label Guidance

Guidelines for Registration of Drug Products Made in Nigeria

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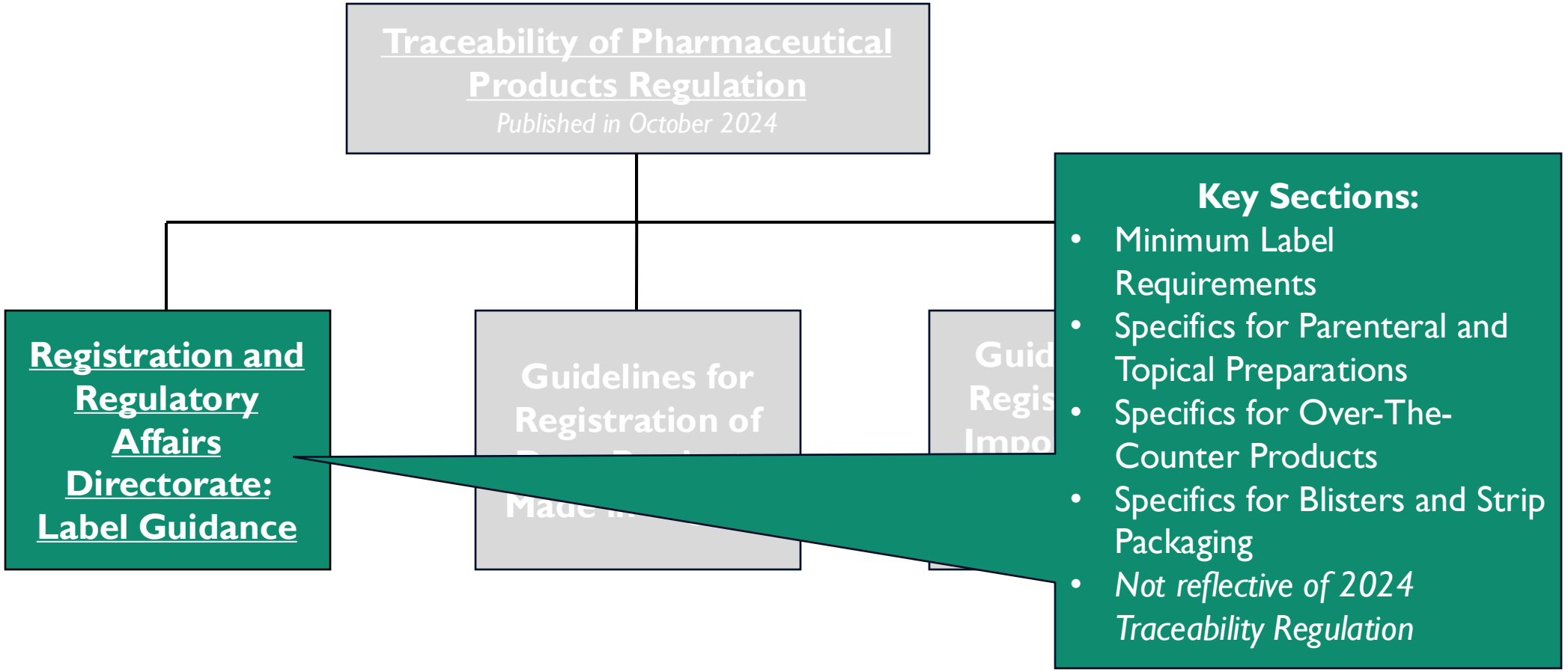
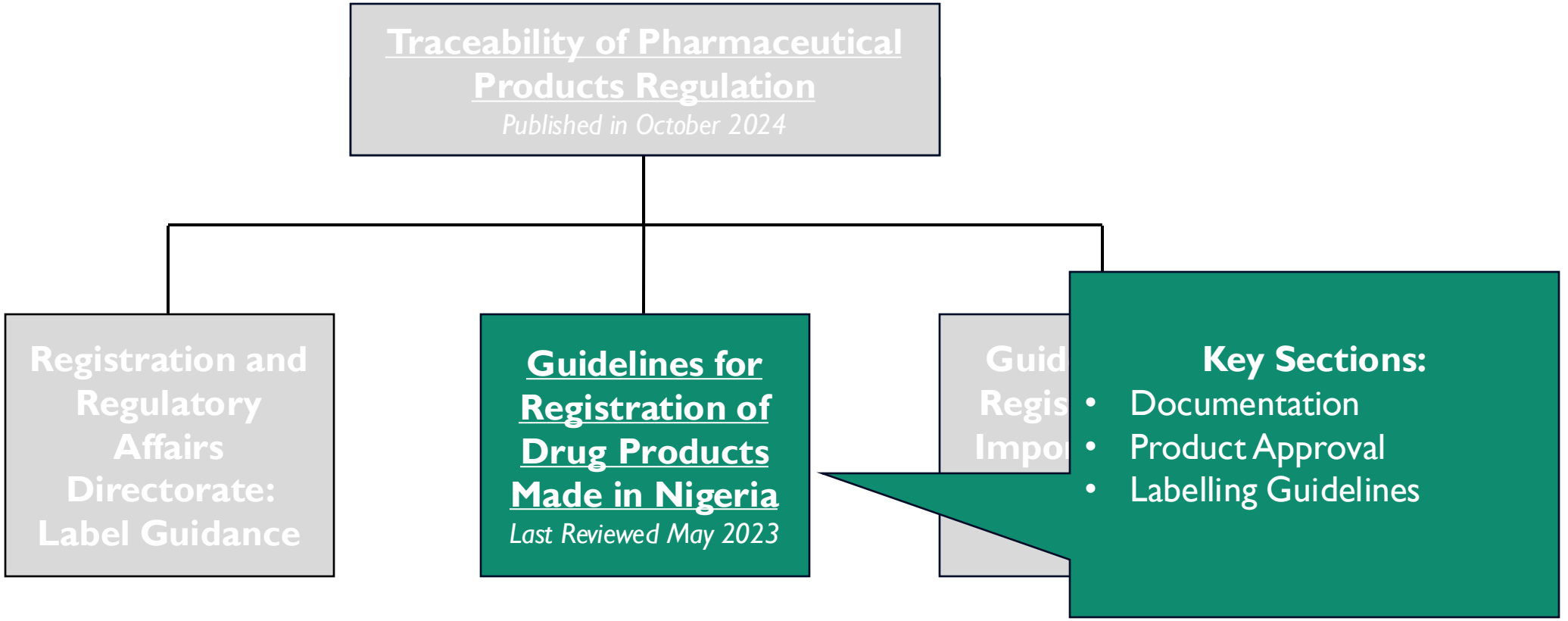
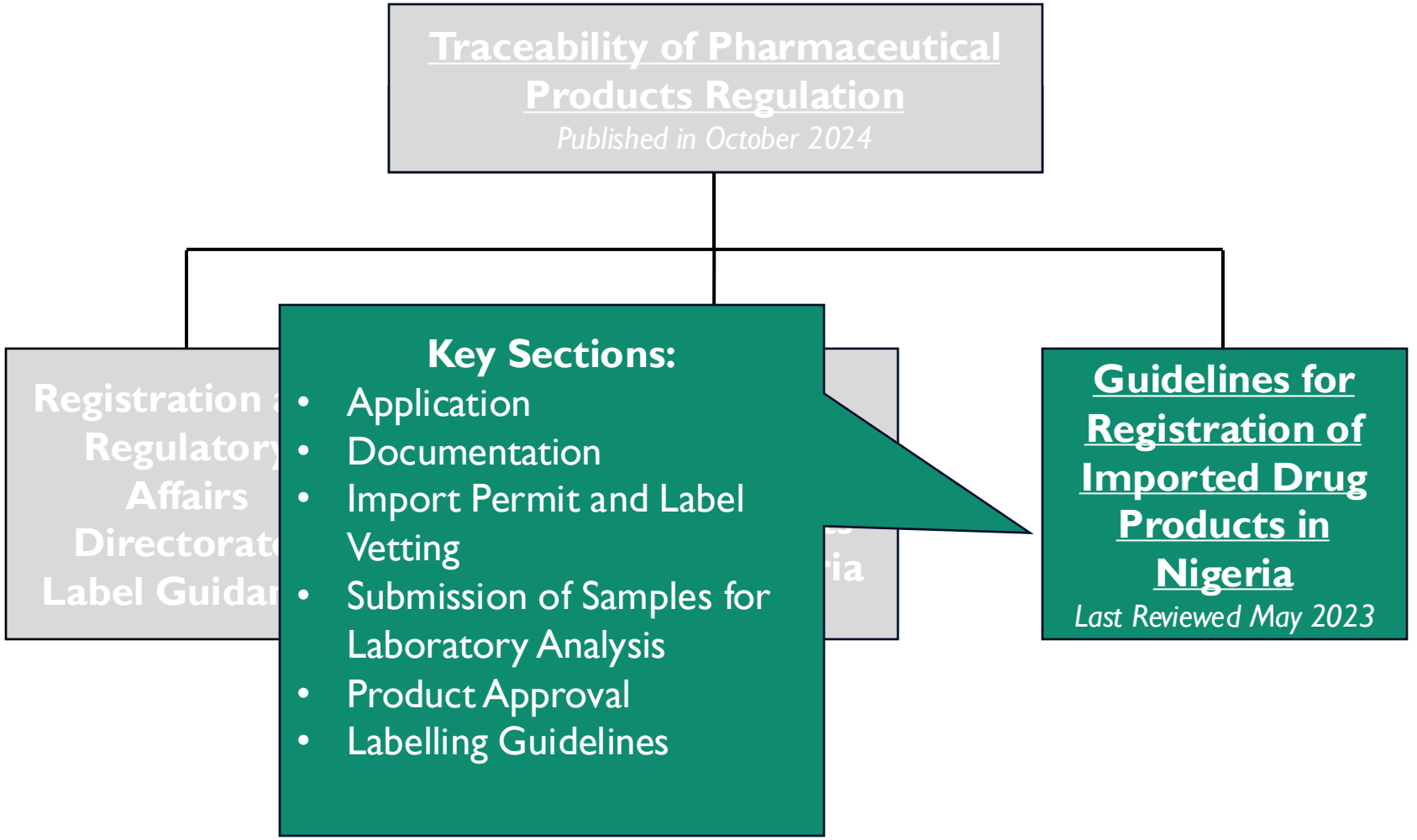
Summary of Regulatory Documents: Nigeria



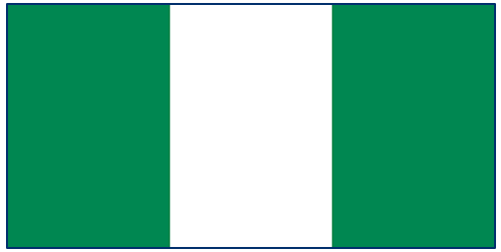
Summary of Regulatory Documents: Nigeria



Summary of Regulatory Documents: Nigeria

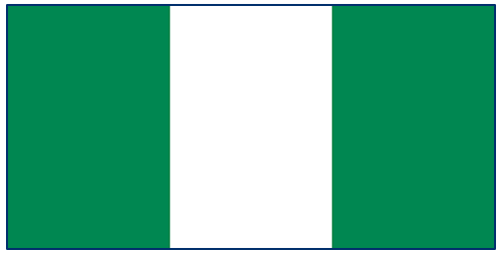


Regulatory Summary: Identification & Labeling



Packaging Type	Requirement	Deadline
Primary or Secondary Trade Item (where primary pack is a trade item, unique identifier shall be assigned to the primary package)	GS1 DataMatrix encoded with GTIN, batch or lot number, expiry date, and serial number	*No phase-in period established under current regulation*
Tertiary pack trade item	GS1 DataMatrix or GS1-128 encoded with GTIN, batch/lot, and expiry	*No phase-in period established under current regulation*
Logistic Unit	Data carrier as stated in GS1 General Specifications encoded with SSCC Where the logistic unit is an orderable trade item, the logistic unit shall be identified with SSCC and the unique identifier	*No phase-in period established under current regulation*

Regulatory Summary: Data Sharing



Requirement	Details	Deadline
Master Data: Trade Item: Brand owner or manufacturer shall share product master data for drug and related product trade items and logistics items as may be required by the agency Location: GLN for organizations and important locations, including locations where items are manufactured and where orders are received, distributed, and dispensed	GTIN: As may be required by the agency GLNs: Data elements in accordance with the GS1 Healthcare GLN guidelines	*No phase-in period established under current regulation*
Event Data:	Pharmaceutical supply chain stakeholders shall electronically capture and share with the agency the unique identifier with associated traceability information, when the product was manufactured, received and distributed or dispensed. The traceability to be captured and shared shall include the date/time information, physical locations, source/destination, GSRN and master data of persons handling product, logistics events, and disposition (revied regulation for additional detail) Aggregation and data retention expectations also defined within regulation	*No phase-in period established under current regulation*

Ghana Draft Regulation Summary

Summary of Draft Regulatory Documents: Ghana

Guideline on Implementation of Identification and Data Capture for Pharmaceutical Traceability

Issued as Draft

Note: This drafted regulation is not currently posted online for public consumption (as of January 2025)

Key Sections:

- Technical Specifications of the Unique Identifier
- Technical Specifications of Data Carriers
- Human Readable Interpretation (HRI)
- Traceability Reporting
- Administrative Provisions

South Africa Draft Regulation Summary

Summary of Draft Regulatory Documents: South Africa

Guidelines on the Traceability of Health Products

Drafted in May 2024

Note: This drafted regulation is not currently posted online for public consumption (as of January 2025)

Key Sections:

- General Requirements
- Composition of the Unique Identifier
- Data Carriers (Available Product Identification Keys)
- SAHPRA requirements for each packaging level
- Data Capture
- Requirements for Medicines and Location Master Data Sharing
- Phased Implementation

Additional Resources

Additional Resources

- GHSC-PSM Global Standards Implementation Toolkit (scroll down to see *Global Standards Implementation Guidance for Suppliers*)
- GS1 Healthcare Public Policy Database (registration required)